TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #20-311

DIGEST

Amends 410 IAC 3-3-3 to update and add to the list of disorders all newborns and infants shall be screened for. Amends 410 IAC 3-3-3.5 to set standards for pulse oximetry screenings. Amends 410 IAC 3-3-13 to increase the fee charged for newborn screenings to cover the cost of screening for a new disorder. Effective 30 days after filing with the Publisher.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

410 IAC 3-3-3; 410 IAC 3-3-3.5; 410 IAC 3-3-13

SECTION 1. 410 IAC 3-3-3 IS AMENDED TO READ AS FOLLOWS:

410 IAC 3-3-3 Screening for certain disorders; collection procedures

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 3. (a) Except as provided for in section 2(b) of this rule, all newborns and infants born in the state of Indiana shall be screened for the following:

(1) The following endocrine disorders:
  (A) Congenital adrenal hyperplasia (CAH).
  (B) Hypothyroidism.
(2) The following hemoglobinopathies:
  (A) Sickle cell anemia Hb SS.
  (B) Hb S/C.
  (C) Hb S/beta-thalassemia.
  (D) Other Hb variant including genetic trait.
(3) The following metabolic conditions:
  (A) The following amino acid (AA) disorders (include urea cycle disorders):
    (i) Arginase deficiency (Argininemia).
    (ii) Argininosuccinic aciduria **(Arginosuccinase deficiency).**
    (iii) Biopterin cofactor defects.
    (iv) Citrullinemia, type I.
    (v) Citrullinemia, type II (also called Citron deficiency).
    (vi) Homocystinuria (HCY).
    (vii) Hypermethioninemia.
    (viii) Hyperphenylalaninemia. ~~(also called H-Phe).~~
    (ix) Maple syrup urine disease (MSUD).
    (x) Phenylketonuria (PKU).
    (xi) Tyrosinemia type I.
    (xii) Tyrosinemia type II.
    (xiii) Tyrosinemia type III.
  (B) The following fatty acid oxidation (FAO) disorders:
    (i) 2, 4-dienoyl-CoA reductase deficiency.
    (ii) Carnitine-Acylcarnitine translocase deficiency (CACT).
    (iii) Carnitine palmitoyltransferase deficiency I (CPT IA).
    (iv) Carnitine palmitoyltransferase deficiency II (CPT II).
    (v) Carnitine uptake defect (CUD).
    (vi) Glutaric acidemia. ~~type II.~~
    (vii) Long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD).
    (viii) Medium chain acyl-CoA dehydrogenase deficiency (MCAD).
    (ix) Medium/short chain ~~L-3-hydroxyacyl-CoA~~ **acyl-CoA** dehydrogenase deficiency (M/SCHAD).
    (x) Trifunctional ~~protein~~ **enzyme** deficiency.
    (xi) Very long chain acyl-CoA dehydrogenase deficiency (VLCAD).
    (xii) Medium chain ketoacyl-CoA thiolase deficiency (MCAT).

(C) The following organic acidemia (OA):
(i) 2-Methylbutyrylglycinuria (2-MBG).
(ii) 3-Hydroxy-3-methyl glutaric aciduria (HMG).
(iii) 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC deficiency).
(iv) 3-Methylglutaconic acidemia (3-MGA).
(v) Beta-ketothiolase deficiency.
(vi) Glutaric acidemia type I (GA type I).
(vii) Isobutyrylglycinuria (IBG).
(viii) Isovaleric acidemia (IVA).
(ix) Malonic aciduria (MAL).
(x) Methylmalonic acidemia (MUT or methylmalonyl-CoA mutase).
(xi) Methylmalonic acidemia with cobalamin disorders (CblA and CblB).
(xii) Methylmalonic acidemia with homocystinuria (CblC and CblD).
(xiii) Multiple-CoA carboxybutyric aciduria (2M3HBA).
~~(xiii)~~ **(xiv)** Propionic acidemia.
~~(xiv)~~ **(xv)** 2-Methyl-3-hydroxybutyric aciduria (2M3HBA).

(4) The following other inborn errors of metabolism:
(A) Biotinidase deficiency.
(B) Galactosemia (classic galactosemia or G/G, galactosemia D/G variant and other galactosemia variants).

(5) The following other genetic conditions:
(A) Cystic fibrosis.
(B) Severe combined immunodeficiencies (SCID).
(C) Spinal muscular atrophy. ~~(SMA).~~
(D) Beginning July 1, 2020, Krabbe disease.
(E) Beginning July 1, 2020, Pompe disease.
(F) Beginning July 1, 2020, Mucopolysaccaridosis type 1 (MPS1).

(6) Other genetic conditions that are detectable at birth via newborn screening methods, including, but not limited to, the following:
(A) Tandem mass spectrometry: **amino acid and acylcarnitine analysis.**
(B) High performance liquid chromatography.
(C) Isoelectric focusing.
(D) Time resolved fluoroimmunoassay. ~~immunoreactive trypsinogen (IRT) measurement.~~
(E) ~~Other~~ Enzymatic assay.
(F) Fluorometric assay.
(G) Immunoreactive trypsin (IRT).
(H) Biotinidase.
~~(G)~~ **(I)** DNA mutation analysis.

(b) The responsible physician, midwife, birthing center, or hospital shall collect a specimen of the newborn or infant's blood on a filter paper kit approved by the department. The specimen shall consist of capillary blood obtained by heel puncture and applied directly to the special filter paper. All circles shall be saturated with blood from one (1) side of the filter paper only. All information requested on the form attached to the special filter paper shall be provided. The specimen shall be air dried and then inserted into the protective envelope with complete data. If multiple specimens are forwarded in one (1) envelope, care must be taken to avoid cross-contamination. Completed specimens shall be forwarded to a designated laboratory within twenty-four (24) hours after collection.

(c) The newborn or infant's blood for these tests shall be collected not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth, except as stated in subsections (f) and (g).

(d) When a live birth occurs in a hospital or birthing center, the responsible physician or midwife shall have a specimen of the newborn or infant's blood taken prior to the newborn or infant's discharge from the hospital. If the newborn is discharged from the hospital before twenty-four (24) hours after birth, a blood specimen shall be collected regardless, but collection shall be repeated after forty-eight (48) hours and not later than one hundred twenty (120) hours after birth. The hospital or birthing center shall provide a written notice to the parents, at or before discharge, of the requirements for the newborn to be tested again prior to one hundred twenty (120) hours after birth.

(e) When a live birth occurs in a facility other than a licensed hospital or birthing center, it shall be the responsibility of the physician or midwife in attendance at the birth to ensure that the newborn or infant is referred

to an appropriate facility, such as a physician office, hospital, birthing center, or local health department, and to make the arrangements to obtain and submit a satisfactory blood specimen in accordance with this section. In the absence of an attending physician or midwife, the registrar of births shall refer the newborn or infant immediately to the parent's physician or to the local health department for submission of a specimen in accordance with this section and notify the MCH/NBS immediately.

(f) For preterm or low birth weight (less than two thousand (2,000) grams) newborns or infants, the initial specimen shall be taken not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth. A repeat specimen collection shall be taken not earlier than fourteen (14) days and not later than thirty (30) days after birth or the day of discharge, whichever comes first. Prematurity and transfusion status shall be noted on the request form in the space provided. If the newborn or infant is to receive **total exchange** transfusion, then the specimen for the newborn screening test is to be obtained prior to transfusion, which represents the newborn or infant's own blood. If the pre-transfusion collection occurred before twenty-four (24) hours after birth, a repeat collection shall be taken not earlier than twenty-four (24) hours post-transfusion start time. ~~Additional~~ **A second** repeat collection shall be taken at ~~fourteen (14) days and~~ thirty (30) days or day of discharge, whichever comes first.

(g) Except for newborns and infants described in subsection (f), for newborns or infants within the neonatal intensive care unit (NICU), the initial collections shall be taken not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth. A repeat collection shall be taken at ~~fourteen (14) days and~~ thirty (30) days or day of discharge, whichever comes first.

(Indiana State Department of Health; 410 IAC 3-3-3; filed Nov 7, 1986, 3:30 p.m.: 10 IR 416; filed Sep 17, 1999, 10:42 a.m.: 23 IR 324; errata filed Nov 19, 1999, 9:31 a.m.: 23 IR 814; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

SECTION 2. 410 IAC 3-3-3.5 IS AMENDED TO READ AS FOLLOWS:

410 IAC 3-3-3.5 Pulse oximetry measurement for critical congenital heart disease

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 3.5. (a) **Beginning July 1, 2021,** except:
(1) as provided for in section 2(b) of this rule;
(2) for infants diagnosed with critical congenital heart disease prenatally;
(3) for infants having received echocardiogram diagnostic testing prior to the required pulse oximetry screening;
(4) for infants on supplemental oxygen or respiratory support for noncongenital heart diseases; or
(5) for infants on palliative care;
every newborn shall be given a pulse oximetry screening examination ~~(1)~~ not earlier than twenty-four (24) and ~~(2)~~ not later than forty-eight (48) hours after birth. ~~Preterm newborns or infants shall be given a pulse oximetry screening, including repeat screenings, at or near the time the specimen is taken as provided for in section 3(f) of this rule.~~

(b) For infants exempted under subsection (a)(4), providers shall use best judgment for performing a pulse oximetry screening, after the infant has been removed from oxygen or respiratory support.

~~(b)~~ **(c)** Pulse oximetry screenings shall be taken from pulse oximetry readings on the right hand and ~~one (1)~~ **either** foot.

~~(c)~~ **(d)** A passing pulse oximetry reading is an initial reading or repeat ~~readings~~ **reading,** which is:
(1) greater than or equal to ninety-five percent (95%) on the right hand ~~or~~ **and either** foot **screened in subsection (c);** and
(2) less than or equal to three percent (3%) variance between the right hand and **either** foot **screened in subsection (c).**

~~(d)~~ **(e)** Except as provided in subsection ~~(e),~~ **(f),** newborns who do not pass the initial pulse oximetry reading as described in subsection ~~(c)~~ **(d)** shall have ~~up to three (3)~~ **one (1)** repeat ~~readings~~ **reading following the initial screening** performed ~~at~~ one (1) hour ~~increments~~ **after the initial reading.** If the newborn does not pass ~~one (1) three (3) repeat readings~~ **the initial or repeat reading** as described in subsection ~~(c),~~ **(d),** the newborn shall be immediately ~~referred for cardiology evaluation.~~ **assessed through an established clinical pathway for definitive diagnosis of critical congenital heart disease.**

~~(e)~~ **(f)** Newborns with an initial pulse oximetry reading of less than ninety percent (90%) ~~on~~ **in the** right hand or foot shall be immediately ~~referred for cardiology evaluation.~~ **assessed through an established clinical pathway for definitive diagnosis of critical congenital heart disease.**

~~(f)~~ **(g)** Newborns ~~referred for cardiology evaluation~~ **requiring immediate assessment** as required in either subsection ~~(d)~~ **(e)** or ~~(e)~~ **(f)** shall be given, at a minimum, diagnostic testing via echocardiogram.

(h) Providers shall ensure pulse oximetry screening information, including saturation percentages, is completed on the newborn's screening card or the religious refusal form, if applicable. If an infant meets an exception to pulse oximetry screening under subsection (a), the provider shall ensure that information is reported to the department in the monthly summary report.

(Indiana State Department of Health; 410 IAC 3-3-3.5; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

SECTION 3. 410 IAC 3-3-13 IS AMENDED TO READ AS FOLLOWS:

410 IAC 3-3-13 Newborn screening fund; fees; disposition; reporting requirements

Authority: IC 16-19-3-4; IC 16-41-17-9; IC 16-41-17-10
Affected: IC 16-41-17

Sec. 13. (a) The program involving the department and MCH/NBS as described in this rule shall be funded by the collection of a newborn screening fee for each initial newborn screening performed. The designated laboratory shall assess and collect the full amount of the newborn screening fee from hospitals, birthing centers, public health nurses, physicians, and midwives submitting newborn screening specimens. No surcharge will be assessed, collected, or reported for newborns or infants receiving repeat screens. The accumulated collections from the newborn screening fees shall be submitted on a monthly basis by the designated laboratory to the division of finance at the department. Payments shall be postmarked not later than five (5) days after the close of the preceding month. The designated laboratory shall also submit a monthly report on the number of newborns screened. Revenues submitted by the laboratory shall correspond with the number of newborns screened.

(b) The newborn screening fee shall be one hundred **fifteen** dollars ~~($100)~~ **($115)** based on the projected cost of the program described in this rule and the estimated number of newborns per year. The fees shall be deposited in the newborn screening fund. Funds for the program described in this rule shall be disbursed by the department in accordance with normal procedures prescribed by the state budget agency and the state board of accounts. The fee shall be reviewed annually by the department.

(Indiana State Department of Health; 410 IAC 3-3-13; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

Notice of Public Hearing

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